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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/754,911	01/09/2004	Alice Y. Ting	M0656.70088US01	8718

23628 7590 06/02/2005

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EXAMINER

WESSENDORF, TERESA D

ART UNIT PAPER NUMBER

1639

DATE MAILED: 06/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/754,911

Applicant(s)

TING, ALICE Y.

Examiner

T. D. Wessendorf

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-161 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-161 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-56, drawn to a method for labeling a target protein.
- II. Claims 57-80, drawn to a composition.
- III. Claims 81-94, drawn to nucleic acid, host and process.
- IV. Claims 95-109, drawn to a composition comprising a biotin analog with alkyl at trans-ureido nitrogen of biotin.
- V. Claim 110, drawn to a composition comprising a biotin analog as ketone analog or NBD-GABA.
- VI. Claims 111-121, drawn to a phage display library comprising a biotin ligase mutant.
- VII. Claims 122-145, drawn to a method for identifying a biotin ligase mutant.
- VIII. Claims 146-161, drawn to a method for identifying a biotin analog having specificity for a biotin ligase mutant.

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The inventions are distinct, each from the other because of the following reasons:

Inventions I, VII and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to different methods using different components and steps that produces different results/ compounds with different effects and/or functions. For example, the method of Group I is drawn to labeling a target protein. Group VIII is drawn to a method for identifying a biotin ligase mutant.

Inventions (II, III, IV, V and VI) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to structurally different compounds that have different functions/effects. For example, the composition of Group II is drawn to a protein (i.e., biotin) that differs in structure from the nucleic acid of Group III.

Inventions (I, VII and VIII) and (II, III, IV, V and VI) are unrelated. Inventions are unrelated if it can be shown that

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they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to different statutory subject matter i.e., different methods and structurally different compounds.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and the search required for Group I is not required for Groups II-VII, specifically the literature searches, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention:

If Group I is elected, applicants are to elect a single species from A-D. [The subgroups below are actually genus but are termed species for only the purpose of grouping each distinct compound). A proper species election is for example a species as recited in claim 18.

A. Biotin analog

1. Aliphatic carboxylic acid

2. Substitution at a transureido (N) (the species are recited in claim 4).

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i. Ketone analog

ii.. Azide

iii. NBD-GABA

iv. 1,2-diamine

v. N-alkyne

vi. Tetrathiol

3. Fluorogenic (the species are recited in claim 7).

4. Directly detectable (the species are recited in claim 9).

5. Indirectly detectable label (the species are recited in claim 11).

6. Labeled with a membrane impermeant.

7. Labeled after conjugation to the fusion protein.

8. Labeled with a singlet oxygen radical generator (the species are recited in claim 15).

9. Labeled with an analyte-binding group (the species are recited in claim 18).

10. Labeled with a heavy atom carrier (species are recited in claim 20).

11. Labeled with an affinity tag (species are recited in claim 22).

12. Labeled with a photoactivatable cross-linker (the species are recited in claim 24).

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13. Labeled with a photoswitch (the species are recited in claim 26).

14. Labeled with photolabile protecting group (the species are recited in claim 28).

15. Labeled with a peptide comprising non-naturally occurring amino acid.

B. Cell

1. Eukaryotic (the species are recited in claim 35).

2. Bacterial

C. Acceptor peptide (elect a single peptide sequence from the different Seq. ID. Nos.)

D. Biotin Ligase mutant (elect a single peptide species e.g., single mutant.)

If Group II or Group IV is elected, elect from the following species below (see the list for e.g., A below as in Group I above):

A. Ligase mutant

B. Biotin analog

If Group III is elected, elect the species elect from the following species below (see the list for e.g., A below as in Group I above):

A. Biotin ligase mutant

2, Nucleic acid

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If Group V or VI is elected, elect from the following species below (see the list for e.g., A below as in Group I above):

A. Biotin ligase mutant

If Group VII is elected, elect from the following species below (see the list for e.g., A below as in Group I above):

A. Biotin analog

B. Peptide acceptor

C. Detection system (the species are recited in claim 141).

If Group VIII is elected, elect from the following species below (see the list for e.g., A below as in Group I above):

A. Biotin analog

B. Acceptor peptide

C. Biotin ligase mutant

Each of the species covered in each of the species A-D (actually genus) differs in structure and mode of action. A prior art reference anticipating one species would not render obvious the other species.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held

to be allowable. Currently, claims 1, 57, 81, 95, 110, 111, 122 and 146 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or

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admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

F.P.: Ochiai/Brouwer Rejoinder form paragraph

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection is governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus,

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to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between products claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996).

Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

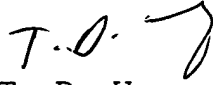
Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (571)272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571)272-0811. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


T. D. Wessendorf
Primary Examiner
Art Unit 1639

tdw

5/27/01